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## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Rehabilitative Services
<b>Virginia Administrative Code (VAC) citation</b>	22 VAC 30 - 50
<b>Regulation title</b>	Policies and Procedures for Administering Commonwealth Neurotrauma Trust Fund Initiative
<b>Action title</b>	2007 Amendment to Regulation as a result of Periodic Review
<b>Date this document prepared</b>	April 28, 2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action*

The regulations to administer the Commonwealth Neurotrauma Initiative (CNI) Trust Fund are essential to maintaining the purpose, operation, and integrity of the program. The CNI Trust Fund is designed to promote medical research into traumatic brain and spinal cord injuries, and to provide treatment and care for individuals who have sustained such injuries. The substantial amendments to the regulation simplify and clarify several sections of the regulation, making it easier to understand. The regulation change will emphasize that the fund is to be used for innovative research and treatment programs and is not to be used as a source for long term funding; this has been an issue with previous grantees. The regulations were also amended to make the reviewing and ranking of grant applications easier to understand and follow by omitting an itemized list of "weighted" criteria with assigned point values. This area has been changed to include a list of criteria for reviewing and ranking of grant applications, but the criteria are not "weighted" with specific point values. The assigned point values will be included in the actual request for proposals document when it is issued. The regulations simplified the language under the Option B, community-based application priorities section, making the submission requirements clearer to the reader. The amended regulation added a provision that the commissioner can reallocate a limited amount of unexpended balances to fund new research in the area of neurotrauma. This is a new provision resulting from budget amendment language approved by the General Assembly.

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

Code of Virginia

§ [51.5-12.4](#). Procedures for grant applications.

The Commissioner of Rehabilitative Services shall promulgate regulations establishing procedures and policies for soliciting and receiving grant applications and criteria for reviewing and ranking such applications, including, but not limited to, goals, timelines, forms, eligibility, and mechanisms to ensure avoidance of any conflicts of interest or appearances thereof. The Commissioner shall receive the recommendations of the Advisory Board prior to promulgating or revising any such regulations.

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.*

The regulations to administer the Commonwealth Neurotrauma Initiative (CNI) Trust Fund are essential to the integrity of the program. The CNI Trust Fund is designed to promote medical research into traumatic brain and spinal cord injuries and to provide treatment and care for individuals who have sustained such injuries. Moneys in the trust fund are to be used solely to support grants for Virginia based researchers, organizations, and institutions that either conduct research into the mechanism of neurotrauma or that provide medical or rehabilitative treatment and care for individuals with such injuries. The amendment to this regulation will clarify that the fund is to be used for innovative research and treatment programs and is not to be used as a source for long term funding. The amended regulation will also provide that the commissioner can reallocate a limited amount of unexpended balances ~~in the fund~~ to fund new research in the area of neurotrauma.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)*

Most sections in this regulation contain only minor technical changes. The following sections contain substantive changes:

22VAC30-50-30 Title of catchline has been changed to Disbursement of funds to more adequately describe this section. Adds a phrase that funds are to be used for the development of innovative, model programs and services for individuals with neurotrauma. Wording has been changed to ensure that "person first" language is used in the regulations

22VAC30-50-60 Section has been amended deleting the timeline for release of a Request for Proposals to allow more leniency to applicants or the advisory board in the deadline due date.

22VAC30-50-70. Title of catchline has been streamlined from Appointment of Grant reviewers and technical advisors to Grant reviewers and technical advisors. The restriction that the chairperson of the advisory board of the Commonwealth Neurotrauma Trust Fund not be able to vote on applications for funds when reviewers and advisors sit as a committee has been removed.

22VAC30-50-80. Section has been amended to stress that grant funds for rehabilitative services are to be used for the development of innovative, community-based rehabilitation programs and services and that when grant funds are not to be used for the long term funding of research projects or service programs.

22VAC30-50-90. Review of applications; stated priorities. This section has been amended to state that the advisory board may fund applicants who seek funds for research projects relevant to rehabilitative as well as medical inquiry. Additionally the detail under Option B was modified in an attempt to make submission requirements clear.

22VAC30-50-100. Reviewing and ranking grant applications. The inclusion of an itemized list of "weighted" criteria with point values assigned to each criterion has been changed to an "unweighted" list of criteria, with specific point values to be assigned in the individual requests for proposals.

22VAC30-50-110. Amount of grant awards; duration and availability of funding. Statement added that the selection of successful applications will be based on available moneys in the fund, the review and ranking of the applications by the advisory board, as well as information from grant reviewers or technical advisors appointed by the board.

22VAC30-50-120. Unexpended funds. This new section has been added as the result of a 2005 budget amendment which states that the commissioner may reallocate up to \$500,000 from unexpended balances in the Commonwealth Neurotrauma Initiative Trust Fund to fund new grant awards for research on traumatic brain and spinal cord injuries.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:*

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

*If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

The proposed regulatory action will provide citizens, applicants, consumers of services and their advocates with information on the Commonwealth Neurotrauma Initiative Trust Fund. The primary advantage of this regulatory action is that the integrity of the Commonwealth Neurotrauma Initiative Trust Fund will be maintained. This action provides an objective means of reviewing and ranking applications to the Fund while allowing for flexibility in distributing the funds during times of economic change. No disadvantages to the public or the Commonwealth have been identified.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

There are no applicable federal requirements.

**Localities particularly affected**

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

No locality will be particularly affected by the proposed regulation.

**Public participation**

*Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.*

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Vanessa S. Rakestraw, Policy Analyst, Department of Rehabilitative Services, 8004 Franklin Farms Drive, Richmond, VA 23229, fax number (804) 662-7696, email: Vanessa.Rakestraw@drs.virginia.gov

Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

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**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b>	No cost to the state
<b>Projected cost of the regulation on localities</b>	No cost to localities
<b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b>	This regulation affects researchers who want to apply for funds from the Commonwealth Neurotrauma Initiative to conduct research into the mechanisms of neurotrauma and to service providers who want to develop innovative rehabilitation and treatment services for persons who have neurotrauma. .
<b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity,</b>	In 2006 the board issued a Request for Proposal and received 16 applications in total. However, of that 16, several entities submitted more than one application: two were from WWRC, 4 were from

<p>including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>VCU and two were from Brain Injury Services, Inc. Thus, a total of 11 entities applied. The board funded 7 of these applicants. Of these 7 applicants, two awards were made to one entity. A total of 6 entities received awards.</p> <p>In 2007, the board issued an RFP and received 21 applications in total: seven were from the University of Virginia, 13 from VCU, and one from another entity. This is 3 entities total that applied. The Board funded six of these applicants. Five awards went to VCU and one award went to UVA, resulting in two entities receiving awards.</p> <p>VCU and UVA have been treated as entities in themselves and have not been broken down by the different departments within VCU or UVA. If they are broken down by departments, the number of entities will change.</p>
<p><b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b></p>	<p>The only projected costs to affected entities are those involved in completing the application requirements to apply for the CNI Trust Funds. However, this cost already exists with the current regulations.</p>

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

As a part of a periodic review, the department requested that the staff and board of the CNI Trust Fund Initiative review this regulation to determine if any amendments were needed to make the regulation consistent with current practices of administering the trust fund. In order to incorporate the recommendations of the staff and board, the department is proceeding with a Notice of Intended Regulatory Action. No other viable alternative is considered to meet the purpose of this regulation.

**Regulatory flexibility analysis**

*Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

This regulation is mandated by state law and there are no applicable alternative regulatory methods. DRS invited input from providers and other stakeholders as the amendments were developed. The proposed changes were recommended by Commonwealth Neurotrauma Initiative Trust Fund Advisory Board to improve administration of the CNI Trust Fund while simplifying the application process for grantees. The existing reporting requirements provides at least 60 days for applicants to submit applications for grant money after a request for

proposal is issued. Applicants must demonstrate in their application for funds how they will carry out the intention of the fund. Applicants must also include a system for measuring outcomes of their proposed projects and for documenting project impact and effectiveness.

There is no projected adverse impact on small businesses. Unless a small business intends to apply for grant funds to conduct research into the mechanisms of neurotrauma or provide treatment for persons with neurotrauma, the amendment does not apply to small business.

**Public comment**

*Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.*

Commenter	Comment	Agency response

No comments were received after the publication of the NOIRA regulation.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

This regulation is not expected to have a direct impact on families. However, a positive indirect impact is expected in that the regulation will assist in providing treatment and research into therapeutic techniques to help persons recover as much as possible from neurotrauma. Treatment and any therapeutic techniques that are developed as a result of research would help reduce related health and welfare problems that occur as a result of neurotrauma

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale

<p>10</p>		<p>"RFP" or "request" means a request for proposals published by the advisory board seeking applications for moneys in the fund.</p>	<p>Wording has been changed to state that requests for proposals are <u>issued</u> by the advisory board. The term "grant" has been inserted to stress that the moneys in the fund are grant moneys.</p>
<p>20</p>		<p>The Commonwealth of Virginia has recognized the need to prevent traumatic spinal cord and brain injuries and <u>is committed to improving</u> the treatment and care of Virginians with traumatic spinal cord and brain injuries.</p> <p>By creating the fund and authorizing the advisory board to administer the fund, the Commonwealth makes available to Virginia-based organizations, institutions and researchers to address these needs.</p> <p>The advisory board seeks to administer the fund in order to carry out the intent of the law in accordance with its authority.</p>	<p>Wording has been changed to emphasize that the Commonwealth is committed to improving the treatment of Virginians with traumatic spinal cord and brain injuries.</p> <p>Wording has been changed slightly to stress that the Commonwealth makes <u>grant funds</u> available to Virginia-based organizations, institutions, and researchers to address these needs.</p> <p>The words "seeks to" has been struck from this sentence to emphasize that the board is administering the fund.</p>
<p>30</p>		<p>Purpose of chapter.</p> <p>shall be allocated for rehabilitative services, i.e., community-based rehabilitative programs for <del>injured</del> individuals with <u>neurotrauma</u>; and 5.0% of the moneys shall be allocated for the Department of Rehabilitative Services' costs for administering and staffing the Commonwealth Neurotrauma Initiative Advisory Board.</p> <p>Those applications for grants to conduct research on the mechanisms and treatment of neurotrauma shall be identified as Option</p>	<p>Catch line has been changed to <u>Disbursement of funds</u> to adequately describe the purpose of this section.</p> <p>Language has been changed to stress that a percentage of the moneys in the fund shall be used for the <u>development of innovative, model programs and services</u>.</p> <p>Wording using the disability first has been changed to Person first language. Injured individuals is now individuals with neurotrauma. Commonwealth Neurotrauma Initiative <u>Trust Fund and</u> Advisory Board adds the words Trust Fund to distinguish between the entities of the fund and the advisory board.</p> <p>This statement has been deleted from this section and relocated to Section 80.</p>

		A applications. Those applications for grants to provide rehabilitative services shall be identified as Option B applications.	
40			No Change
50			Minor sentence restructuring to make this section easier to read.
60		publishing requests for proposals from time to time  Each application for a grant must be received in response to an actual request for proposals and by a deadline specified in the request, which will be no fewer than 60 days following publication of the request.	The advisory board now issues a request for a proposal in place of publishing a request for a proposal. The deadline requirement for responding to requests for proposals has been deleted from the regulation. Each request for proposals that is issued will have its own deadline published.
70		Appointment of grant reviewers and technical advisors	Title of catch line changed to <u>Grant</u> reviewers and technical advisors and minor wording changes have been done to make the section easier to read.
80		Each application shall clearly state a purpose to seek funds to carry out a program consistent with Option A or Option B.	Each application shall clearly state a purpose to seek funds <u>for projects to conduct research on the mechanisms and treatment of neurotrauma which shall be referred to as "Option A," or to develop innovative, model community-based rehabilitative programs and services for individuals with neurotrauma, which shall be referred to as "Option B."</u> The definitions of Option A and Option B have been relocated from section 30 to section 80, and the definitions are more descriptive. The following statement has been added to stress that these funds are not intended for long-term funding of projects or programs.: <u>Neither Option A nor Option B grants are intended for long-term funding of research projects or service programs.</u>
90		<b>Review of applications; stated priorities.</b>  In reviewing applications for	Catch line has been changed to <u>Submission of applications.</u>  In reviewing applications <u>submitted for</u>

		<p>grant awards, whether Option A or Option B, the advisory board will give priority to applications that:</p> <p>2. Include a system for measuring outcomes and documenting project impact and effectiveness, including any anticipated long-term effect of the proposed project.</p> <p>3. Provide the means for consumer involvement in the design, implementation and evaluation of the project as relevant to the intention of the proposed project;</p> <p>4. Identify sources of funds, if known, and fundraising strategies to be used in sustaining the proposed project following termination of a grant award as relevant to the intention of the proposed project;</p>	<p>grant awards, whether Option A or Option B, the advisory board will <u>accept</u> applications that: meet the delineated criteria. If applications do not meet the required criteria, they will not be accepted for consideration.</p> <p>These criteria for applications have been moved from this section to the next section which discusses the specific criteria for reviewing and rating applications.</p>
100		Ranking and reviewing.	<p>Catch line changed to <u>Reviewing and ranking grant</u> applications because applications are reviewed before they are ranked. All of the ranking criteria have been placed under this one section. Specific weights for each criteria have been removed. If any criteria is to receive more weight in the ranking process, it will be stated in the request for proposal.</p>
110		The selection of successful applications will be made based on (i) availability of moneys in the fund and, (ii) the criteria listed in this chapter	<p>The selection of successful applications will be made based on (i) <u>availability of moneys in the fund</u> (ii) <u>the review and ranking of the applications according to the criteria listed in this chapter,</u> (iii) <u>information from grant reviewers or technical advisors which the board may appoint to assist in evaluating applications,</u> and (iv) <u>the advisory board's assessment of those applications which further the intentions and the purpose of the fund.</u></p> <p>Provides more information on the process of selection of recipients of grant funds.</p>
	120		<p><b><u>22VAC30-50-120. Unexpended funds.</u></b></p> <p><u>Notwithstanding any other law to the contrary, the commissioner may reallocate up to \$500,000 from unexpended balances in</u></p>

			<p><u>the Commonwealth Neurotrauma Initiative Trust Fund to fund new grant awards for research on traumatic brain and spinal cord injuries.</u></p> <p>This new section allows the commissioner to reallocate any moneys remaining in the balance of the Fund to new grant awards.</p>
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Enter any other statement here